NOV 22 2011 K112687
p1/3

Welch Allyn

510(k) Summary

[As described in 21 CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Contact Person: Kevin Crossen, Director Regulatory Affairs
Phone: (315) 685-2609
Fax: (315) 685-2532
E-mail: Kevin.Crossen@welchallyn.com

Date Prepared: September 2, 2011

Trade Name: Welch Allyn Connex® Vital Signs Monitor 6000 Series

Common Name: Monitor,physiological,patient(without arrhythmia detection or alarms)

Device Classification: Class II

Classification Reference: 870.2300, Cardiac Monitor (including Cardiotachometer and Rate Alarm)

Classification Product Code: MWI

Predicate Devices: **Welch Allyn Vital Signs Monitor – CVSM 6000 Series**
Vital Signs Monitor, CVSM 6000 Series, CVSM
Welch Allyn, Inc.
510(k) Number K110516

Description of Device:

The proposed modified Connex Vital Signs Monitor 6000 Series (CVSM) is the same device that was cleared under K110516; in particular, the indications for use for vital signs measuring/monitoring subsystem of the proposed device are the same as those cleared under K110516. In the modified device, the Welch Allyn Application Framework (Framework) – has been included as a separate subsystem. The Framework is general purpose software that allows medical device and non-medical device software applications to run on the Framework independently of, and isolated from, the CVSM's vital signs monitoring functionality.

Welch Allyn

Indications for Use:

The VSM 6000 Series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for:

- noninvasive blood pressure,
- pulse rate,
- noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and
- body temperature in normal and axillary modes.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments.

The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework, general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting.

This product is available for sale only upon the order of a physician or licensed health care professional.

Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate CVSM 6000 device. This version of the CVSM also includes the Welch Allyn Applications Framework (Framework) for running software applications developed by Welch Allyn or third-party providers. The Framework is general purpose software that allows medical device and non-medical device software applications to run on the Framework independently of, and isolated from, the CVSM's vital signs monitoring functionality. Welch Allyn or third-party software applications will incorporate program interfaces, data structures, and communications protocols prescribed by Welch Allyn in its Application Developer Toolkit (ADK). These ADK specifications conform to the architectural control points used in the Framework. Available software applications may, at the end user's option, be included as part of the purchase of the CVSM, pre-loaded on the Application Framework, or uploaded after purchase of the CVSM by utilization of an embedded service tool for installation.

Non-Clinical Tests:

Verification and validation were conducted to ensure expected performance of the CVSM 6000 and to demonstrate the addition of the Framework does not affect the functionality or performance of the CVSM and that applications run on the

WelchAllyn

Framework are isolated from and independent of CVSM vital signs monitoring functionality and do not control or otherwise affect the performance of the CVSM.

The following standards were applied to the modified device.

- IEC 60601-1:Ed. 2: 1988 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (with A1: 1991+A2:1995)
- IEC 60601-1-2: Ed. 3: 2007 - Medical Electrical Equipment – Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test
- IEC 60601-1-4: Consolidated Ed. 1.1: 2000 - General Requirement for Safety: Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-1-8: Ed. 1: 2003 - General requirements for safety - Collateral Standard: Alarm Systems - Requirements, tests and guidances - General requirements and guidelines for alarm systems in medical equipment (with A1:2006)
- IEC 60601-2-30: Ed. 2: 1999 - Manual, electronic or automated sphygmomanometers (with A1:2003, A2:2006)
- ISO 9919: Ed. 2: 2005 - Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- ISO 14971: Ed. 2: 2007 - Medical devices - Application of risk management to medical devices

Clinical Performance Data:
No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

Conclusion:
Based on the information presented in this 510(k) premarket notification, Welch Allyn's Connex® Vital Signs Monitor 6000 Series as modified is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 22 2011

Welch Allyn, Inc.
c/o Mr. Kevin Crossen
Director Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K112687
Trade/Device Name: Connex® Vital Signs Monitor 6000 Series
Regulatory Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: October 24, 2011
Received: October 25, 2011

Dear Mr. Crossen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112687
p1/2

Indications for Use

510(k) Number (if known): K

Device Name: Welch Allyn Connex® Vital Signs Monitor 6000 Series

Indications for Use:

The VSM 6000 Series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for:

- noninvasive blood pressure,
- pulse rate,
- noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and
- body temperature in normal and axillary modes.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments.

The optional Masimo Rainbow SET® and accessories are indicated for the continuous noninvasive monitoring of total hemoglobin concentration of adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Optional compatible weight scales (e.g., Health o meter®) can be used for height, weight, and BMI input.

Prescription Use (Part 21 CFR 801 Subpart D)	x	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112687

K112687
p2/2

Indications for Use (continued)

The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting.

This product is available for sale only upon the order of a physician or licensed health care professional.